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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,432	07/06/2001	Robert Kleiman	511-051	3374

39602 7590 06/13/2005

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EXAMINER	
JIANG, SHAOJIA A	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 06/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/899,432	KLEIMAN ET AL.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2005 and 18 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-3, 5-6, 8-9, 11-12, 14-15, 17-18, 20-21, 23-24, 26-27, 29-30, 32-33, 35-36, 86-87, and 89-90* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are
2,3,5,6,8,9,11,12,14,15,17,18,20,21,23,24,26,27,29,30,32,33,35,36,38,39,41,42,44,45,47,48,50,51,53,54,56,57,59,60,62,63,65,66,68,69,71,72,74,75,77,78,80,81,83,84,86,87,89 and 90.
Continuation of Disposition of Claims: Claims withdrawn from consideration are
38,39,41,42,44,45,47,48,50,51,53,54,56,57,59,60,62,63,65,66,68,69,71,72,74,75,77,78,80,81,83 and 84.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 4, 2005 has been entered.

This Office Action is in response to Applicant's request for continued examination (RCE) filed April 4, 2005, and amendment and response to the Final Office Action (mailed January 13, 2004), filed January 18, 2005 wherein the instant specification has been amended as to page 14, lines 5-10; claims 2-3, 5-6, 8-9, 11-12, 14-15, 17-18, 20-21, 23-24, 26-27, 29-30, 32-33, 35-36, 86-87, and 89-90 have been amended. It is noted that claims 1, 4, 7, 10, 13, 16, 19, 22, 25, 28, 31, 34, 37, 40, 43, 46, 49, 52, 55, 58, 61, 64, 67, 70, 73, 76, 79, 82, 85, and 88 have been cancelled previously and Claims 38-39, 41-42, 44-45, 47-48, 50-51, 53-54, 56-57, 59-60, 62-63, 65-66, 68-69, 71-72, 74-75, 77-78, 80-81, and 83-84 drawn to an invention nonelected with traverse (see the previous Office Action May 20, 2003).

Currently, claims 2-3, 5-6, 8-9, 11-12, 14-15, 17-18, 20-21, 23-24, 26-27, 29-30, 32-33, 35-36, 38-39, 41-42, 44-45, 47-48, 50-51, 53-54, 56-57, 59-60, 62-63, 65-66, 68-69, 71-72, 74-75, 77-78, 80-81, 83-84, 86-87, and 89-90 are pending in this application.

Claims 2-3, 5-6, 8-9, 11-12, 14-15, 17-18, 20-21, 23-24, 26-27, 29-30, 32-33, 35-36, 86-87, and 89-90 as amended now are examined on the merits herein.

Applicant's amendment filed January 18, 2005 with respect to the rejection of claims 5-6, 11-12, 17-18, 23-24, 29-30, 35-36 and 89-90 made under 35 U.S.C. 112 second paragraph for the use of the indefinite recitations of record stated in the Office Action dated January 13, 2004 have been fully considered and found persuasive to remove the rejection since the indefinite recitations have been removed. Therefore, the said rejection is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-3, 5-6, 8-9, 11-12, 14-15, 17-18, 20-21, 23-24, 26-27, 29-30, 32-33, 35-36, 86-87, and 89-90 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's amendment submitted January 18, 2005 with respect to these amended claims have been fully considered but is deemed to insert new matter into the claims.

The omission of an essential element of the invention "the composition further comprising one or more of the salts of fatty acids according to the formula R^1-COO^-M^+ wherein R1 comprises CH3-(CH2)7-CH=CH-CH2-(CH2)x-, and x is 6, 8, 10 and 12 and M+ is a monovalent alkali metal ion." in claims 2, 8, 14, 20, 26, 32, 86; the omission of an essential element of the invention "wherein the composition further comprises one or more mixed esters according to the formula R1-COO-R2 wherein R1 comprises CH2-(CH2)7-CH=CH-CH2-(CH2)x-, and x is 6, 8, 10 and 12, and R2 is an alkyl group or other aliphatic group, preferably of 1 to 12 carbon atoms" in claims 3, 9, 15, 21,27, 33, 87 are deemed to raise new matter issue, i.e., an issue regarding whether the inventor had possession of a broader, more generic invention. See, e.g., >PIN /NIP, Inc. v. Platte Chem. Co., 304 F.3d 1235, 1248, 64 USPQ2d 1344, 1353 (Fed. Cir. 2002). As noted in MPEP 2163, A claim that omits an element which applicant describes as an essential or critical feature of the invention originally disclosed does not comply with the written description requirement. See Gentry Gallery, 134 F.3d at 1480, 45 USPQ2d at 1503; In re Sus, 306 F.2d 494, 504, 134 USPQ 301, 309 (CCPA 1962).

In the instant case, the specification as originally filed clearly discloses that these two limitations "the composition further comprising one or more of the salts of fatty acids according to the formula R^1-COO^-M^+ wherein R1 comprises CH3-(CH2)7-CH=CH-CH2-(CH2)x-, and x is 6, 8, 10 and 12 and M+ is a monovalent alkali metal ion" and "wherein

the composition further comprises one or more mixed esters according to the formula R1-COO-R2 wherein R1 comprises CH2-(CH2)7-CH=CH-CH2-(CH2)x-, and x is 6, 8, 10 and 12, and R2 is an alkyl group or other aliphatic group, preferably of 1 to 12 carbon atoms" are **essential and critical elements** of the claimed invention.

Moreover, the specification as originally filed does not provide support for "the polar hydrophilic salts **further comprising** one or more of the salts of fatty acids according to the formula R^1-COO^-M^+ wherein R1 comprises CH3-(CH2)7-CH=CH-CH2-(CH2)x-, and x is 6, 8, 10 and 12 and M+ is a monovalent alkali metal ion", but teaches that "the polar hydrophilic salts which **are** salts of long chain fatty acids" (see page 14 of the specification). Nowhere can the recitation "the polar hydrophilic salts **further comprising**" the particular salts be found in the specification.

Furthermore, the new limitation "the polar hydrophilic salts" added into the independent claims herein has changed the claimed invention or at least changed and broader the scope of the claimed invention, since the salts of long chain fatty acids are **not** necessarily "the formula R^1-COO^-M^+ wherein R1 comprises CH3-(CH2)7-CH=CH-CH2-(CH2)x-, and x is 6, 8, 10 and 12 and M+ is a monovalent alkali metal ion".

Consequently, there is nothing within the instant specification which would lead the artisan in the field to believe that Applicant was in possession of the invention as it is now claimed. See *Vas-Cath Inc. v. Mahurkar*, 19 USPQ 2d 1111, CAFC 1991, see also *In re Winkhaus*, 188 USPQ 129, CCPA 1975.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-3, 5-6, 8-9, 11-12, 14-15, 17-18, 20-21, 23-24, 26-27, 29-30, 32-33, 35-36, 86-87, and 89-90 as amended now are rejected under 35 U.S.C. 103(a) as being unpatentable over Katz et al. (5,952,392) in view of ARQUETTE et al. (WO 9920224) and Katz (4,874,794) and Katz (5,070,107).

Katz et al. (5,952,392) discloses that long chain fatty acids broadly including oleic acid (C18, one double bond, see col.2 lines 12-15; col. line 5-8, col.4 line 26-28) or monounsaturated long chain alcohols broadly (e.g., C18-C28, or octadecenol and docosenol) in their effective amounts with a physiologically compatible carrier (e.g., cream or ointment applied to skin, or aqueous solution, see Example 12, 14-15 at col.20 line 34-35 and col.22 line 39-40 and 64) are useful in a pharmaceutical composition for topical application and intramuscular and intravenous injections, and methods of treating viral infections and virus-induced and inflammatory disease of skin and membranes because these compounds have antiviral activity. See abstract, col.1 lines 10-15 and 20-47; col.3 lines 18-21; Examples 14-15 at col.22-23. Katz et al. also discloses that the effective amount of docosenol in the pharmaceutical composition is about 10% to 12% w/w (by weight, within the instant claim, see col.6 line 64, col.16 lines 59-60 and claims 10-11).

The prior art does not expressly disclose the employment of monounsaturated long chain alcohols in combination with long chain fatty acids salts herein in a pharmaceutical composition, which may further comprising the fatty acid esters herein, in a method for treating virus-induced and inflammatory disease of skin and membranes.

Arquette et al. (WO 9920224) discloses a pharmaceutical composition comprising the instant fatty alcohols at least 10% by weight (see particularly abstract and page 3 lines 15-22), jojoba oil (known to contain the instant fatty acids, see page 4 entirely), and the instant fatty acid esters in their various percentages (see page 4-8) with a physiologically compatible carrier for topical applications (see abstract and claims 1-12

Katz et al. (4,874,794) discloses that the effective amounts of long chain fatty alcohols broadly (e.g., C20-C26) with a physiologically compatible carrier in a pharmaceutical composition for topical application for methods of treating viral infections and skin inflammations are 0.1 to 25 percent by weight. See abstract, col.3 lines 63-68, claims 1-2.

Katz et al. (5,070,107) discloses that the effective amounts of long chain fatty alcohols broadly (e.g., C27-C32) with a physiologically compatible carrier in a pharmaceutical composition for topical application and intramuscular and intravenous injections for methods of treating viral infections and skin inflammations are 0.1 mg to 2 g/per 50kg of body weight. See abstract, col.3 lines 63-68, claims 1-2.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the instant monounsaturated long chain alcohols in combination with the instant fatty acids salts herein in a pharmaceutical composition, which may further comprising the instant fatty acid esters herein, in methods for treating virus-induced and inflammatory disease of skin and membranes, and to optimize the effective amounts of active agents in the composition herein to be administered.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the instant monounsaturated long chain alcohols in combination with the instant fatty acids salts herein in a pharmaceutical composition, which may further comprising the instant fatty acid esters herein, in methods for treating virus-induced and inflammatory disease of skin and membranes since long chain fatty acids broadly or monounsaturated long chain alcohols broadly in their effective amounts with a physiologically compatible carrier are known to be useful in pharmaceutical compositions for topical application and intramuscular and intravenous injections, for methods of treating viral infections and virus-induced and inflammatory disease of skin and membranes because these compounds have antiviral activity based on Katz et al. Moreover, the instant fatty alcohols at least 10% by weight, or about 10% to 12% w/w by weight of docosenol in the pharmaceutical composition disclosed by Katz et al. (5,952,392), or 0.1 mg to 2 g/per 50kg of body weight also disclosed by Katz et al. (5,070,107 and 4,874,794), the instant fatty acids, and the instant fatty acid esters in their various percentages with a physiologically compatible carrier are known to be

useful in a pharmaceutical composition for topical applications according to Arquette et al.

It has been well settled that pharmaceutically acceptable salts of the pharmaceutical compound are obvious over the pharmaceutical compound. Thus, the same fatty acids salts are deemed obvious over the same fatty acids taught by the cited prior art, having the same therapeutic effects and usefulness in treating virus-induced and inflammatory disease of skin and membranes.

Therefore, one of ordinary skill in the art would have reasonably expected that combining the instant fatty alcohols, the instant fatty acid salts, and the instant fatty acid esters taught in Arquette et al. in a pharmaceutical composition to would improve the therapeutic effect for treating virus-induced and inflammatory disease of skin and membranes since these components are known to be useful in treating virus-induced and inflammatory disease of skin and membranes.

Since all active composition components herein are known to useful to treat virus-induced and inflammatory disease of skin and membranes, it is considered prima facie obvious to combine them into a single composition to form a third composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

Additionally, one of ordinary skill in the art would have been motivated to optimize the effective amounts of active ingredients in the composition because the optimization of known effective amounts of known active agents to be administered according the disclosures of Katz et al. and Arquette et al., is considered well within the

skill of artisan. It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Applicant's remarks filed January 18, 2005 with respect to this rejection of made under 35 U.S.C. 103(a) of record in the previous Office Action have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art. These remarks are believed to be adequately addressed by the obvious rejection presented above.

Additionally, contrary to Applicant's assertion that Katz '392 does not disclose the specific physiologically compatible carrier, Katz '392 clearly discloses that a physiologically compatible carrier in a form e.g., cream or ointment applied to skin, or aqueous solution, as discussed above. Moreover, the instant claims merely recite "a physiologically compatible carrier".

Further, Applicant's arguments that none of Katz references ('392, '794, or '107) teach or disclose the medical effects of the instant salts of fatty acids or mixed esters, are not found convincing. As discussed above, fatty acids and their esters are known to be in a pharmaceutical composition for topical application and intramuscular and intravenous injections, and methods of treating viral infections and virus-induced and inflammatory disease of skin and membranes. It has been well-settled that the non-toxic salts of the compound, i.e., the non-toxic salts of fatty acids to be employed in the same

treatment as fatty acids, would be considered to be **obvious**, since one of ordinary skill in the art would recognize that the non-toxic salts of fatty acids and fatty acids would have same or substantially similar activities as anti-viral agents (see MPEP 2143.02).

Applicant's testing data in the specification at pages 23-26 have been fully considered with respect to the nonobviousness and/or unexpected results of the claimed invention over the prior art and but are not deemed persuasive. The results on the tests of the employment of the tested composition within the instant claim in vitro in the specification have been fully considered but are not deemed persuasive as to unexpected results over the prior art for reasons discussed below. The results on test on the composition herein, demonstrate that the composition herein has anti-viral effects, as taught and suggested by the cited prior art herein. Therefore, the results herein are clearly expected and not unexpected based on the cited prior art. Expected beneficial results are evidence of obviousness. See MPEP § 716.02(c). In this regard, it is noted that the specification provides no side-by-side comparison with the closest prior art in support of nonobviousness for the instant claimed invention over the prior art.

Therefore, the evidence presented in Examples herein is not seen to support the nonobviousness of the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Anna Jiang, Ph.D.
Primary Examiner
Art Unit 1617
June 2, 2005